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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/584,373

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Bjarne Due Larsen

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EXAMINER

AUDET, MAURY A

ART UNIT

PAPER NUMBER

1654

MAIL DATE

DELIVERY MODE

12/18/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/584,373

Applicant(s)

LARSEN, BJARNE DUE

Examiner

MAURY AUDET

Art Unit

1654

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 June 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11 and 68-88 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-11, 68-88 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 23 June 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB-08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

- I. Claims 1-11, 68-77, drawn to an isopeptide represented by general formula (I); e.g. H- first amino acid moiety - second amino acid moiety – OH; with iso variant therein; wherein R4 and R5 are independently any hydrophobic group.
- II. Claims 78-84, drawn to an isopeptide represented by the general formula (II); e.g. H- first amino acid moiety - second amino acid moiety – OH; with iso variant therein; comprising 2 6-member rings.
- III. Claim 86-88, method for modulating gap junctional communication in a population of cells comprising administering an effective amount of an isopeptide represented by general formula (I); e.g. H- first amino acid moiety - second amino acid moiety – OH; with iso variant therein; wherein R4 and R5 are independently any hydrophobic group; to the population of cells, thereby modulating gap junctional communication between the cells.
- IV. Claim 86-88, drawn to a method of preventing and/or treating a pathological condition involving impaired gap junctional communication comprising administering to an individual in need thereof a therapeutically effective amount of an isopeptide represented by general formula (I); e.g. H- first amino acid moiety - second amino acid moiety – OH; with iso

variant therein; wherein R4 and R5 are independently any hydrophobic group.

Lack of Unity

An international and a national stage application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept ("requirement of unity of invention"). Where a group of inventions is claimed in an application, the requirement of unity of invention shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression "special technical features" shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art. An international or a national stage application containing claims to different categories of invention will be considered to have unity of invention if the claims are drawn only to one of the following combinations of categories: (1) a product and a process specially adapted for the manufacture of said product; or (2) a product and a process of use of said product; or (3) a product, a process specially adapted for the manufacture of the said product, and a use of the said product; or (4) a process and an apparatus or means specifically designed for carrying out the said process; or (5) a product, a process specially adapted for the manufacture of the said product, and an apparatus or means specifically designed for carrying out the said process. If multiple products, processes of manufacture or uses are claimed, the first invention of the category first mentioned in the claims of the application and the first recited invention of each of the other categories related thereto will be considered as the main invention in the claims, see PCT Article 17(3)(a) and 1.476(c).

No 'Special' Technical Feature

The 'technical feature' running through the claims is an isopeptide, the general formula of which as defined on page 7 of the specification is:

H - first amino acid moiety - second amino acid moiety - OH.

[Wherein:]

An "amino acid moiety" is defined as a moiety comprising an amino acid. An amino acid may be any amino acid, e.g. [ANY OF THE 20 NATURAL AMINO ACIDS:] alanine, arginine, asparagine, aspartic acid, cysteine, glutamic acid, glutamine, glycine, histidine, isoleucine, leucine, lysine, methionine, phenylalanine, proline, serine, threonine, tryptophan, tyrosine, valine, and sarcosine. Such a moiety may additionally comprise a further chemical group or groups, for example a hydrophobic group, for example an aromatic carbon ring, for example, a 6-membered aromatic carbon ring. Included within

the definition is a moiety which does not comprise any further chemical groups, such that it consists of an amino acid, i.e. the amino acid moiety comprises an amino acid only, without the addition of further chemical groups.

Demuth et al. (US 7,381,537; 102(e) date 5/3/03 v. Applicant's earliest effective priority date 12/23/03) **expressly teach the H-first amino acid moiety - second amino acid moiety - OH formula/structure** (see sol. 12, line 48-49; see also Tables 5 (6 examples) and 7 (4 examples); entire document); as evidenced by example:

H-iso-Asp-Ala-OH

Thus, the technical feature is known. Therefore it does not constitute a 'special' technical feature, and the claims lack unity of invention.

Requirement for Election of a Single Fully Defined Isopeptide (Group I or II) as the Invention

As described above, isopeptides of the general formula **H-first amino acid moiety - second amino acid moiety - OH**, such as **H-iso-Asp-Ala-OH**, are known in the art. Each dipeptide isopeptide is a distinct peptide. Which requires an individual sequence and/or structure search of each dipeptide and its modifications, as there is no overlapping search possible. The search of each and every dipeptide and its modifications would thus constitute an undue search burden.

Table 1 of the specification evidences 138 distinct dipeptide isopeptides. Therefore, irrespective of which Group of I-IV is elected as the invention, Applicant must elect a single dipeptide as the isopeptide, e.g. Ala-Glu – and expressly claim the structure of the dipeptide into the formula; as the invention (not species), to which the elected Invention group will be searched. However, the Examiner is open to searching the variable groups off of the elected dipeptide isopeptide; namely R1 to R5, but NOT a, b, x, and y; as the latter four

variables would remove the isopeptide from being a dipeptide – and Applicant's only working examples in Table 1 are those of dipeptide isopeptides.

This requirement is not to be taken as an election of species, but rather as an election of a single invention, since each compound is assumed to be a patentably distinct invention, in the absence of evidence to the contrary.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

In re Ochiai/Brouwer Rejoinder

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to

maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Claim Objections

Claims 2, 7, 13, 16, and 19 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

Claims 5 is objected to under 37 CFR 1.75(c), as being of improper dependent form for depending from another method of making claim 4 and failing to depend from the product claim 1 (like method of making claim 4) further limit the subject matter of a previous claim. Applicant is required to amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MAURY AUDET whose telephone number is (571)272-0960. The examiner can normally be reached on M-Th. 7AM-5:30PM (10 Hrs.).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MA, 12/16/2009

/Maury Audet/
Examiner, Art Unit 1654
Full Sign. Auth. Program